In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-29V

Filed: November 21, 2014

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JEANNIE UETZ,	*	
	*	Special Master
Petitioner,	*	Hamilton-Fieldman
	*	
v.	*	Dismissal Decision; Zostavax
	*	Vaccination; Boostrix Vaccination
SECRETARY OF HEALTH	*	Vaccine Act Six Month Residual
AND HUMAN SERVICES,	*	Requirement; Lumbar Puncture; Surgical
	*	Intervention.
Respondent.	*	
* * * * * * * * * * * * * * * * * * *		

Carol L. Gallagher, Carol L. Gallagher, Esq., Linwood, NJ, for Petitioner.
Darryl R. Wishard, United States Department of Justice, Washington, DC, for Respondent.

DECISION GRANTING RESPONDENT'S MOTION TO DISMISS[1]

On January 13, 2014, Jeannie Uetz ("Petitioner") filed a petition for compensation under the National Vaccine Injury Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act" or "Program"), alleging that she developed "headaches, myalgia, fatigue and fever, necessitating a surgical procedure," as a result of the administration of the Zostavax[3] and Boostrix (Tetanus

[1] Because this published decision contains a reasoned explanation for the action in the case, the undersigned intends to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347 § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). As provided by Vaccine Rule 18(b), each party has 14 days within which to file a motion for redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). In the absence of such motion, the entire decision will be available to the public. *Id.*

[2] National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2006).

[3] Although the petition cited two vaccines that were administered to Petitioner on September 29, 2012 (Zostavax and Boostrix), Petitioner's counsel states in her Opposition to Respondent's Motion to Dismiss that she is "cognizant of the fact that [] Zostavax is not covered

Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine) vaccinations on September 29, 2012. Petition ("Pet.") at 1, ECF No. 1.

After a review of the petition and supporting documents, Respondent filed a Motion to Dismiss, asserting that Petitioner did not establish that she suffered from the residual effects of a vaccine-related injury for more than six months and that Petitioner's lumbar puncture procedure on September 30, 2012, does not qualify as a "surgical intervention and inpatient hospitalization" under the Vaccine Act. Resp't's Motion to Dismiss at 2-3, ECF No. 11. Therefore, Respondent argues, the claim must be dismissed for failure to state a claim upon which relief may be granted. For the reasons stated herein, Respondent's Motion is GRANTED.

I

FACTUAL BACKGROUND

Petitioner was vaccinated with Zostavax and Boostrix on September 29, 2012. Pet'r's Ex. 2 at 2. On September 30, 2012, Petitioner was transported by ambulance to St. Charles Medical Center for outpatient care for severe headache and fever. Pet'r's Ex. 3 at 6-8; Pet'r's Ex. 4 at 7-10. Petitioner was treated by Dr. Meske, who ordered several diagnostic tests of Petitioner, including a CT scan of the brain and a lumbar puncture. Pet'r's Ex. 4 at 16, 24, 26; Pet'r's Ex. 4 at 10. Petitioner's cerebral spinal fluid ("CSF") tested as normal, and her blood and CSF cultures were negative. Pet'r's Ex. 4 at 15-16. She was prescribed Percocet for pain and discharged from the emergency room the same day (September 30, 2012). *Id.* at 16.

On October 3, 2012, Petitioner treated with Dr. Allred, her primary care provider ("PCP"), for headache, continued myalgia, and low back pain. Pet'r's Ex. 5 at 6. Dr. Allred opined that Petitioner's headache was "most likely an immune reaction but could have been a viral reaction," and that he "would like [Petitioner] to stay off work for another week." Pet'r's Ex. 5 at 7. The low back pain was also noted to stem from the lumbar puncture Petitioner had undergone on September 30, 2012 during her outpatient visit to St. Charles Medical Center. Pet'r's Ex. 4 at 10. Petitioner returned to work on October 10, 2012, and continued to work until she retired on March 15, 2013. Pet'r's Ex. 1 at 3; Pet'r's Ex. 10 at 1-2.

There were no medical records submitted for the period between October 10, 2012 and May 15, 2013. On May 15, 2013, Petitioner returned to Dr. Allred for a "Welcome to Medicare" visit; she had no identified complaints at this visit and no mention was made of the September 2012 incident or any lingering symptoms. Pet'r's Ex. 5 at 93-95. In a medical record dated June 4, 2014, from a visit to Dr. Allred for a reason unrelated to the vaccine or its aftereffects, Dr. Allred noted "no residual after effects from her vaccination reaction but she did have six months of persistent symptoms." Pet'r's Ex. 11 at 1.

Petitioner avers in her affidavit that she continued to experience muscle pain and fatigue on August 29, 2013, well after the six month time period stemming from vaccine administration.

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under the Vaccine Act; however, it was one of two vaccines administered to petitioner . . . and therefore, it was incorporated into the petition." Pet'r's Opp. at 1, ECF No. 14.

Pet'r's Ex. 1 at 3. The affidavit of Petitioner's husband, Robert Uetz, attests that Petitioner had to retire from her job on March 15, 2013 due to headaches, fatigue, and difficulty concentrating. He further averred:

> she had issues well into the summer of 2013 and even today she continues to suffer with headaches, muscle aches, irritability, moodiness, mental confusion, fatigue, occasionally has trouble with spelling and simple math, sometimes has trouble with sleeping, gets chilled easily and has trouble warming up. When her hands are cold, she can't do simple tasks and complains of extreme pain, and she is clumsy and drops things.

Pet'r's Ex. 10 at 3.

II

LEGISLATIVE HISTORY AND APPLICABLE LEGAL STANDARD

Congress established the Vaccine Program in 1988. *See* 42 U.S.C. §300aa-1-34. The goals of the Vaccine Program were to "compensate vaccine-injured persons and to protect the nation's vaccine supply by limiting the exposure of vaccine manufacturers to resource-depleting lawsuits." *Spooner v. Sec'y of Health & Human Servs.,* No. 13-159V, 2014 WL 504728, at *5 (Fed. Cl. Spec. Mstr. Jan. 16, 2014). *See also Bruesewitz v. Wyeth LLC,* 131 S.Ct. 1068, 1072 (U.S. 2011).

To proceed with a claim for compensation under the Vaccine Act as originally enacted, a petitioner must have "suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." 42 U.S.C. § 300aa-11(c)(1)(D)(i). "Congress included the 6 month petition requirement 'to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine.' H.R.Rep. No. 100-391(I), at 699 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, -373 . . . [T]his provision, along with the other petition requirements, is intended to restrict eligibility to the compensation program." *Cloer v. Sec'y of Health & Human Servs.,* 654 F.3d 1322, 1335 (Fed. Cir. 2011), *aff'd*, 133 S.Ct. 1886 (2013).

In 1999, a connection between the rotavirus vaccine and intussusception, a gastrointestinal injury in children, was discovered. *See* Centers for Disease Control and Prevention, Withdrawal of Rotavirus Vaccine Recommendation, 48 Morbidity & Mortality Wkl. Rep't. No. 43 (Nov. 5, 1999), *available at* http://www.cdc.gov.mmwr/preview/mmwrhtml/mm4843a5.htm. *See Spooner*, 2014 WL 504728, at *6. Although intussusception is a serious injury, most patients who suffer from intussusception recover quickly after medical intervention, and do not experience lasting effects for more than 6 months. *See* Revisions and Additions to the Vaccine Injury Table, 66 Fed. Reg. 36735, at 36737 (proposed July 13, 2001) ("[M]ost patients with intussusception recover after immediate treatment and do not suffer lasting complications for more than 6 months."). As a result, "petitioners who claimed that the rotavirus vaccine caused their child's intussusception, were often denied compensation [in claims brought under the Vaccine Act]." *Spooner*, 2014 WL 504728, at *6. To maintain the

requirement that eligibility for compensation under the Act be restricted to those seriously injured, but to make allowance for those petitioners whose injuries, such as intussusception, were severe but short-lived, Congress amended subsection 11(c)(1)(D) of the Act in 2000 to include "or (iii) suffered such illness, disability, injury or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention to correct such illness, disability, injury or condition, and...." *Spooner*, 2014 WL 504728, at *6 (citing Health Resources & Services Admin., *National Vaccine Injury Compensation Program: Addition of Vaccines Against Rotavirus to the Program*, 64 FR 40517-01 (July 23, 1999)).

The current version of the Vaccine Act thus has two avenues for living vaccinees to establish eligibility for compensation under the Act: either the vaccinee "(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine," or the vaccinee "(iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention." 42 U.S.C. §300aa-11(c)(1)(D)(i)-(iii).

A petitioner must satisfy the requirement of more than six months of residual effects or of surgical intervention coupled with inpatient hospitalization as "a condition precedent to filing a petition for compensation." *Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d 1322, 1335 (Fed. Cir. 2011), *aff'd*, 133 S. Ct. 1886 (2013). As with all elements of a vaccine claim, the conditions precedent must be proven by preponderant evidence. 42 U.S.C. § 300aa-13(a)(1)(a); *Black v. Sec'y of Health & Human Servs.*, 93 F.3d 781, 785-87 (Fed. Cir. 1996). "A potential petitioner must do something more than merely submit a petition and an affidavit parroting the words of the statute" to go forward with a claim under the Act. *Black v. Sec'y of Health & Human Servs.*, 33 Fed. Cl. 546, 550 (1995), *aff'd*, 93 F.3d 781 (Fed. Cir. 1996) (internal citations omitted). "He or she must submit supporting documentation which reasonably demonstrates" that the injury or its sequelae lasted more than six months, or that surgical intervention and inpatient hospitalization took place. *Id.*

III

ANALYSIS

A. Petitioner's claim fails to meet the requirements of 42 U.S.C. §300aa-11(c)(1)(D)(i)

In her Motion to Dismiss, Respondent argues that Petitioner's claim fails to meet the requirements of 42 U.S.C. §300aa-11(c)(1)(D)(i) because Petitioner has not submitted preponderant evidence that she suffered the residual effects of her vaccine injury for at least six months from the date of vaccination. The undersigned agrees.

The Vaccine Act states in pertinent part that the petitioner must have: "(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." 42 U.S.C. § 300aa-11(c)(1)(D)(i). While both parties in this case offered evidentiary arguments concerning the onset of Petitioner's symptoms, the date of symptom onset is not relevant to the 6 month residual effect inquiry; Petitioner's "six

months" runs from September 29, 2012, the date of her vaccination. Pet'r's Ex. 2 at 2. In this case, six months following vaccination is March 29, 2013.

Unfortunately, Petitioner in this case has failed to provide preponderant evident that she suffered "residual effects or complications" from her September 29, 2012 vaccination through at least March 29, 2013. Although her affidavit and that of her husband state that she continued to suffer effects from the vaccine reaction itself, and from the lumbar puncture, for more than six months, there is simply no contemporaneous documentation to support that assertion. Petitioner saw her PCP, Dr. Allred, on October 3, 2012, to follow up on her emergency room visit, and he directed her to stay off of work for another week. Pet'r's Ex. 5 at 7. After that, the medical records are silent. The medical record closest in time to the six months, the record of the "welcome to Medicare" visit of May 15, 2013, does not even mention the September 30, 2012 ER visit. Pet'r's Ex. 5 at 93. It is silent as to any aftereffects of the vaccine or the puncture, and instead notes no active complaints. *Id.* On the other hand, the note from the visit to Dr. Allred of June 4, 2014, is completely unrelated to any condition for which Petitioner had sought treatment at that time and is therefore unpersuasive. Pet'r's Ex. 11 at 1.

Contemporaneous medical records "warrant consideration as trustworthy evidence" because the information from the patient is related to the treaters to facilitate diagnosis and treatment, and '[w]ith proper treatment hanging in the balance, accuracy has an extra premium." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). The absence of any contemporaneous medical records in this case for the period between October 3, 2012 and March 29, 2013, the majority of the six month statutorily required period, speaks volumes. And while subsequent treatment records can constitute persuasive evidence of prior events under certain circumstances, the subsequent record that might have been persuasive in this case – that from May 15, 2013 – makes no mention of the vaccine-related injury, and therefore does not support Petitioner's case. Pet'r's Ex. 5 at 93.

Finally, the undersigned finds that the June 4, 2014 record appears to have been prepared for purposes of the litigation of Petitioner's claim: its language mimics the language of the statute, it was out of context, and it bears no relationship to any condition for which Petitioner was being seen that day. Pet'r's Ex. 11 at 1. It therefore bears none of the indicia of reliability that the undersigned would rely upon to find it a credible piece of evidence on this issue.

The undersigned therefore finds that the residual effects of a vaccine-caused injury did not persist for six months after Petitioner's vaccination date.

B. Petitioner's claim fails to meet the requirements of 42 U.S.C. §300aa-11(c)(1)(D)(iii)

Respondent's Motion to Dismiss also argues that the lumbar puncture procedure Petitioner underwent on September 30, 2012, does not qualify as a "surgical intervention and inpatient hospitalization" under the Vaccine Act. 42 U.S.C. § 300aa-11(c)(1)(D(iii); *Spooner*, 2014 WL 504728. The undersigned agrees.

The Vaccine Act states in pertinent part that the petitioner must have: "(iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization **and** surgical intervention." 42 U.S.C. § 300aa-11(c)(1)(D)(i)-(iii) (emphasis

added). Both Respondent and Petitioner briefed the issue of whether a lumbar puncture constitutes a "surgical intervention" under the Act.

The undersigned now concludes that it is unnecessary to decide this issue in the context of this case. The statute is written in the conjunctive; that is, a petitioner must have experienced *both* a surgical intervention and an inpatient hospitalization as a result of the vaccine injury in order to be eligible for compensation under the Act. Respondent asserts that Petitioner was not hospitalized at the time she had the lumbar puncture or at any other time as a result of the vaccination. Resp't's Motion to Dismiss at 3, ECF No. 11. Petitioner did not rebut this assertion, and both the medical records and Petitioner's affidavit support the conclusion that Petitioner was not admitted to the hospital as a result of her vaccine injury. Pet'r's Ex. 1 at 2. Rather, she was transported to the ER by ambulance in the early morning hours of September 30, 2012, and left from the ER later that same afternoon. Pet'r's Ex. 3 at 6; Pet'r's Ex. 4 at 16.

Because the undersigned concludes that Petitioner did not suffer an injury from the vaccine "which resulted in inpatient hospitalization", it is unnecessary to determine whether the lumbar puncture itself constituted a surgical intervention. Petitioner is not eligible for compensation under this subsection of the Act.

IV

CONCLUSION

The undersigned is sympathetic to Petitioner's assertion that she suffered what appears to have been an acute and intense, albeit brief, reaction to the vaccines she received on September 29, 2012. However, based on the record as a whole, Petitioner has not demonstrated that she experienced the residual effects of her alleged vaccine-related injury for at least six months as required by the Vaccine Act (Section 11(c)(1)(D)(i)), nor has Petitioner demonstrated that her case fulfills the "surgical intervention and inpatient hospitalization" statutory alternative to the six month residual requirement set forth in Section 11(c)(1)(D)(iii) of the Vaccine Act. **Therefore Respondent's Motion to Dismiss is GRANTED. In the absence of a motion for review, the Clerk shall enter judgment accordingly.**

IT IS SO ORDERED.

/s/ Lisa D. Hamilton-Fieldman
Lisa D. Hamilton-Fieldman
Special Master